Claims

1. A formulation for the lubrication of the oral cavity in humans or animals, wherein said formulation comprises a water-soluble or water-dispersible form of at least one isolated and purified casein phosphoprotein, or salt thereof.

2. A formulation for the lubrication of the oral cavity in humans or animals, wherein said formulation comprises, a water-soluble or water-dispersible form of at least one isolated and purified casein phosphoprotein, or salt thereof, complexed with at least one bioactive constituent, wherein the bioactive constituent is selected from the group consisting of calcium phosphate and calcium phosphate admixed with at least one other bioactive.

3. The formulation of claim 1 or claim 2 wherein the casein phosphoprotein is selected from the group consisting of: : α-casein, β-casein, κ-casein, and mixtures thereof.

4. The formulation of claim 1 wherein the amount of phosphoprotein present in the formulation is between 0.5 and 20% by weight.

5. The formulation of claim 1 wherein the amount of phosphoprotein present in the formulation is between 2% and 7%.

6. The formulation of claim 2, wherein the amount of casein calcium phosphate complex present in the formulation is between about 0.5 and 20% by weight.

7. The formulation of claim 2, wherein the amount of casein calcium phosphate complex present in the formulation is between about 2% and 7%.

8. The formulation of claim 2, wherein said bioactive constituent is an antimicrobial agent.

9. The formulation of claim 8, wherein the antimicrobial agent is selected from the group consisting of: halogenated diphenyl ethers, such as: 2',4,4'-trichloro-2-hydroxy-diphenyl ether (Triclosan); phenolic compounds, including phenol and its homologues, such as: 2-methyl-phenol, 3-methyl-phenol, 4-methyl-phenol, 4-ethyl-phenol, 2,4-dimethyl-phenol, 3,4-dimethyl-phenol, 2,6-dimethyl-phenol, 2,2-methylene bis (4-chloro-6-bromo-phenol); mono- and poly-alkyl and aromatic halophenols, including -p-chlorophenols such as: methyl-p-chlorophenol, ethyl-p-chlorophenol, n-propyl-p-chlorophenol, n-butyl-chlorophenol; -o-chlorophenols; p-bromophenols; -o-

bromophenols; resorcinol and its derivatives, such as: n-methyl hexyl resorcinol; bisphenolic compounds and halogenated carbanilides.

10. The formulation of claim 9, wherein the antimicrobial agent is selected from the group consisting of: glycerol, ethanol sorbitol, mannitol, sodium benzoate, methyl-p-hydroxybenzoate, ethyl-p-hydroxybenzoate, N-propyl p-hydroxybenzoate, butyl-p-hydroxybenzoate, phenoxy ethanol and quaternary ammonium salts, benzethonium chloride, and diisobutyl-phenoxyethoxyethyl dimethyl benzyl ammonium chloride.

11. The formulation of claim 8, wherein said antimicrobial agent is ethanol and/or one or more zinc salts.

12. The formulation of any one of claims 1 to 11, wherein said formulation is incorporated into a formulation selected from the group consisting of: chewing gum, lozenges, foods, beverages, confectionary, pharmaceutical compositions, toothpaste creams or gels, or mouthwashes or spray solutions.

13. The formulation of claim 12 wherein said formulation is incorporated into a chewing gum.

14. The formulation of claim 12 wherein said formulation is incorporated into a lozenge.

15. The formulation of any one of claims 1 to 14, wherein said formulation further comprises a viscosity modifier.

16. The formulation of claim 15, wherein said viscosity modifier is selected from the group consisting of: proteins, mucin, including synthetic and natural mucin, glycoproteins, hydrolysed proteins, globulin, albumin, statherin, alginate, cellulose and cellulose derivatives, carboxymethyl cellulose, irish moss, gum tragacanth, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, hydroxy ethyl cellulose (Natrosol), sodium carboxymethyl cellulose, colloidal silica such as finely ground Syloid, laponite (any form of laponite, such as laponite DF), hectorite, calcium montmorillonite, acid activated bleaching earth and palygorskite.

17. The formulation of claim 15 wherein said viscosity modifier is casein.

18. The formulation of any one of claims 1 to 17 wherein said formulation additionally comprises a salivary stimulator.

19. The formulation of claim 18 wherein the salivary stimulator is selected from the group consisting of: pilocarpine and salogen.

20. The formulation of claim 18 wherein said salivary stimulator is selected from the group consisting of: oil of spearmint, peppermint, wintergreen, sassafras, clove, sage,

eucalyptus, marjoram, cinnamon, lemon, and orange, and methyl salicylate, sucrose, lactose, maltose, dextrose, laevulose, sorbitol, xylitol, d-tryptophan, dihydrochalcones, sodium cyclamate, perillartine, APM (aspartylphenylalanine, methyl ether) and saccharine.

21. The formulation of any one of claims 1 to 20 which is spray-dried prior to use.

22. The formulation of any one of claims 1 to 21 which additionally comprises one or more vitamins or minerals.

23. The formulation of claim 22 wherein said vitamin is selected from the group consisting of: Vitamin A, Vitamin C, Vitamin D, Vitamin D_1, Vitamin D_3, Vitamin E, Vitamin K, Vitamin K_1, Vitamin B complex, Vitamin B_1, Vitamin B_2, Vitamin B_6, Vitamin B_{12}, folate, cytamen, and nicotinate.

24. The formulation of claim 22 wherein said mineral is selected from the group consisting of: calcium, phosphate, fluoride, magnesium, barium, strontium, zinc, iron, nickel, aluminium, copper, tin, fluorophosphate, cobalt, sodium, potassium, chloride, bromide, iodide and oxide.

25. A method for lubrication of the oral cavity of a human or animal wherein said method comprises administration to said human or animal of a therapeutically effective amount of a formulation comprising a water-soluble or water-dispersible form of at least one isolated and purified casein phosphoprotein, or salt thereof.

26. A method for the lubrication of the oral cavity of a human or animal wherein said method comprises administration to said human or animal of a therapeutically effective amount of a formulation comprising a water-soluble or water-dispersible form of at least one isolated and purified casein phosphoprotein, or salt thereof, complexed with at least one bioactive constituent, wherein the bioactive constituent is selected from the group consisting of calcium phosphate and calcium phosphate admixed with at least one other bioactive.

27. The method according to claim 25 or claim 26 wherein said formulation is a formulation according to any one of claims 1 to 24.

28. A method for stimulation of saliva production in a human or animal wherein said method comprises administration to said human or animal of a therapeutically effective amount of the formulation of claim 1 or claim 2 together with at least one salivary stimulator.

29. The method of claim 28 wherein the salivary stimulator is selected from the group consisting of: pilocarpine and salogen.

30. The method of claim 28, wherein said salivary stimulator is selected from the group consisting of: oil of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, and orange, and methyl salicylate, sucrose, lactose, maltose, dextrose, laevulose, sorbitol, xylitol, d-tryptophan, dihydrochalcones, sodium cyclamate, perillartine, APM (aspartylphenylalanine, methyl ether) and saccharine.

31. A method for treatment and/or prevention of xerostomia in a human or animal wherein said method comprises administration to said human or animal of a therapeutically effective amount of the formulation of any one of claims 1 to 24.

32. A method for the treatment and/or prevention of tooth decay in a human or animal, said method comprising administration to said human or animal of a therapeutically effective amount of the formulation according to claim 1 or 2.

33. The method according to claim 32, wherein said tooth decay is tooth erosion.

34. A method for providing one or more vitamins and/or minerals to a human or an animal said method comprising administration to said human or animal of a therapeutically effective amount of the formulation of any one of claims 22 to 24.

35. A method for the treatment and/or prevention of mouth odour or halitosis in a human or animal requiring said treatment or prevention, wherein said method comprises administering to the human or animal a therapeutically effective amount of the formulation according to claim 1 or 2.

36. A method for the treatment and/or prevention of mouth odour or halitosis in a human or animal requiring said treatment or prevention, wherein said method comprises administering to the human or animal a therapeutically effective amount of the formulation according to any one of claims 8 to 11.

37. A process for the preparation of an oral lubrication formulation, wherein said process comprises:

(i) adding a water-soluble or water-dispersible form of at least one casein phosphoprotein, and phosphate ions, to an aqueous solution and stirring until the casein is dispersed;

(ii) adding an aqueous solution of calcium ions, with stirring, to the solution formed in part (i), at a pH of 6.5 or greater, and optionally;

(iii) spray drying the product of step (ii).

38. The process according to claim 37, wherein the pH of the solution at, or after, the addition of calcium ions, is between about 6.5 to 10.

39. A process for the preparation of an oral lubrication formulation, wherein said process comprises:

(i) adding a water-soluble or water-dispersible form of at least one casein phosphoprotein to an aqueous solution and stirring until the casein is dispersed; and optionally

(ii) spray drying the product of step (i).